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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,162	11/19/2003	Hsing-Wen Sung	S&T-125	6771

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	
MAIL DATE	**DELIVERY MODE**
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,162	SUNG ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-9 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-9 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5 Sheets
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-4,7-9 and 11-20 are pending and the subject of this Office Action. Claims were cancelled in the Applicants' response filed on 10 October 2007.

Election/Restriction

Applicants' election of Group I, claims 1-20, with traverse in the response filed on 10 October 2007, is acknowledged. Examiner acknowledges the cancellation of claims 5-6, 10, and 21-41. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)), and hereby deemed final.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4,7-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a medical device where the medical device also comprises, in pertinent part, a biodegradable apparatus. However, the specification only discloses art to supports a single biodegradable apparatus, a stent. As a result, the specification does not provide a written description useful to any person skilled in the art to which it pertains, or with which it is most nearly connected.

Claims 1-4,7-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn, in pertinent part, to a medical device that comprises a "crosslinking agent." The specification is written broadly, however, simply advising of "a crosslinker, such as genipin, its derivatives, analog, stereoisomers and mixtures thereof" (Specification, p. 8, paragraph 23, lines 7-8). The listing of this non-exacting reference is insufficient to meet the written description provision of 35 U.S.C. 112, first paragraph. Albeit crosslinking agents are known by skilled artisans in the chemical art, generally, the specification should be clear as to what does and does not comprise a crosslinking agent for purposes of this invention.

In short, the specification is lacking sufficient written description to support the genus disclosed in claim 1, because the crosslinking agent is not sufficiently and completely disclosed. As a matter of law, an adequate written description requires more than a mere statement that the

matter claimed is part of the invention accompanied by reference to potential compounds. Disclosure of the compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4,7-9 and 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent Application No. 10/520,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '878 patent application, like the instant invention, claims a biodegradable stent with a bioactive agent that is cross-linked, with genipin, for example where the biological agent may be chitosan and the bioactive agent may be a growth factor or ApoA-I Milano. The methods articulated in claims 1-28 of the '251 patent overlap in scope with the methods articulated in claims 1-4,7-9 and 11-20 of the instant invention.

This is a provisional rejection, because the claims have not, in fact, been patented.

In looking in continuity data, it is noted that applicant has numerous pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, pending patent applications with the same or similar subject matter include, but are not limited to 11/130787; 10/929047; 10/906239; 10/827673; 10/811413; and 10/916170.

Claim Rejections – 35 U.S.C. §102(b)

The following is a quotation of 35 U.S.C. §102(b), which forms the basis for all obviousness rejections set forth in this office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

For the purpose of examination herein, the pending claims are given their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969).

Biodegradable apparatus is interpreted as a stent. Crosslinking agent is interpreted as comprising a modified or unmodified biomolecule, an organic molecule, an inorganic molecule, or a combination of biomolecules, organic molecules, or inorganic molecules.

Claims 1, 4, 8-9, 11-12, 16, and 18-20 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,500,013 [hereinafter referred to as "Buscemi et al"].

Buscemi et al disclose a history of stent development, using, for example, (1) materials made of epsilon-caprolactone, glycoside, and L-lactide (Col. 1, lines 66-67); (2) a stent formed using electron beam radiation that may be compounded with an x-ray opaque material (Col. 2, lines 15-18); and (3) the copolymerization of an optically active lactide and epsilon caprolactone in the presence of a tin ester of carboxylic acid, which is biodegradable (Col. 2, lines 56-60).

The invention in Buscemi et al is a biodegradable stent, saturated with drugs, that has a matrix strengthened by, for example, polylactic acid (Col. 3, lines 44-49). The tubular main body of the stent includes an outer and an inner surface (Col. 4, lines 21-23). The main body of the stent includes a film covering the inner surface, which is formed by conventional methods such as solution casting (Col. 5, lines 14-18). The biodegradable materials for the main body of the stent include polyglycolic acid, polylactic acid, polycaprolactone, collagen or other connective proteins, and/or copolymers of these materials as well as composites and combinations (Col. 6, lines 11-30).

Buscemi et al also disclose that drugs are incorporated into the stent using techniques known in the art such as simple mixing or solubilizing with polymer solutions or coating onto an already formed film or fiber, etc. (Col. 12, lines37-43). The fibers can contain anti-thrombogenic drugs and also, drugs or biologically active agents can be incorporated to the film layer, promoting release of drugs or agents at different rates (Col. 12, lines 47-58), including aspirin, tissue plasminogen activators, growth factors, thromboxane inhibitors, growth factors, genetic materials and complete expression genes, etc (Col. 12, lines 64-67 through Col. 13, lines 1-10). Buscemi et al also disclose inhibit or control the formation of thrombus or thrombolytics, and prevent smooth muscle cell growth on the inner surface wall of vessels (Col. 12, lines 59-66).

In light of the foregoing, claims 1, 4, 8-9, 11-12, 16, and 18-20 are clearly anticipated by Buscemi et al.

Claim Rejections – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this office action:

> (a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purpose of examination herein, the pending claims are given their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969).

Biodegradable apparatus is interpreted as a stent. Crosslinking agent is interpreted as comprising a modified or unmodified biomolecule, an organic molecule, an inorganic molecule, or a combination of biomolecules, organic molecules, or inorganic molecules.

Claims 2, 3, 13 and 15 are rejected under 35 U.S.C. §103(a) as being obvious over Buscemi et al in view of U.S. Patent No. 5,272,172 [hereinafter referred to as "Fujii et al"] as evidenced by Vaya, Ampara, et al., "Red Blood Cell Aggregartion and Primary Hyperlipoproteinemia," 15 October 1993, *Thrombosis Research*, Vol. 72, Issue 2, 15 October

1993, pages 119-126 (Abstract as included, rather than article in its entirety is primary reference).

The teachings of Buscemi et al, *supra*, are incorporated herein by reference in total.

Fujii et al teach that "Cape Jasmim (*jasminoides Ellis*) ... has long been known to have pharmacological effects such as an anti-arteriosclerosis agent, a blood coagulation inhibitor and a cholagogue, and geniposide as a typical active component of Cape Jasmim" (Col. 1, lines 19-24). Fujii et al also teach iridoid derivatives and their pharmacologically permissible salts, including for example, methyl (4aS, 7aS)-6,7-expoxy-1, 4a, 5, 6, 7, 7a-hexahydro-1-hydroxy-7-(hydroxymethyl)-cyclopenta[c]pyran-4-carboxylate (Col. 5, lines 42-43), to be anti-hyperlipemia drugs and to have cholagogue actions (Col. 1, lines 39-52).

It is welll-understood in the pharmaceutical art that hypercholesterolemia and hyperlipemia share common etiologies. *Please see* Vaya, Ampara, et al. (Abstract). Furthermore, it is well-understood that in evaluating the same, the following parameters are usually measured: "fibrinogen (Fbg), plasmatic lipids, apolipoproteins, glucose, HbA_1c and membrane erythrocyte lipids: cholesterol (C) and phospholipids (PL)." *Id.* Furthermore, it is understood that there is a direct correlation between erythrocyte aggregation with fibrinogen and apolipoproteins. *Id.*

Due to the overlapping subject matter of treating atherosclerotic and hyperlipidemic conditions resultant from erythrocyte aggregation, one of ordinary skill in the art would be motivated to combine the teachings of Buscemi et al with the teachings of Fujii et al to conclude that a biodegradable stent with medications containing genipin or an epoxy compound, or a biological material to treat hypercholesterolemia would be *prima facie* obvious over prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05 November 2007

Alicia Hughes

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER